



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Parts 720, 721, and 723**

**[EPA-HQ-OPPT-2014-0650; FRL-9944-47]**

**RIN 2070-AJ94**

**Significant New Uses of Chemical Substances; Updates to the Hazard Communication Program and Regulatory Framework; Minor Amendments to Reporting Requirements for Premanufacture Notices**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing changes to the existing regulations governing significant new uses of chemical substances under the Toxic Substances Control Act (TSCA) to align these regulations with revisions to the Occupational Safety and Health Administration's (OSHA) Hazard Communications Standard (HCS), which are proposed to be cross referenced, and with changes to the OSHA Respiratory Protection Standard and the National Institute for Occupational Safety and Health (NIOSH) respirator certification requirements pertaining to respiratory protection of workers from exposure to chemicals. EPA is also proposing changes to the significant new uses of chemical substances regulations based on issues that have been identified by EPA and issues raised by public commenters for Significant New Use Rules (SNURs) previously proposed and issued under these regulations. Additionally, EPA is proposing a minor change to reporting requirements for premanufacture notices (PMNs) and other TSCA section 5 notices. EPA expects these changes to have minimal impacts on the costs and burdens of complying, while updating the significant new

use reporting requirements to assist in addressing any potential effects to human health and the environment.

**DATES:** Comments must be received on or before [*insert date 60 days after date of publication in the **Federal Register***].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2014-0650, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand deliver or delivery of boxed information, please follow the instructions at: <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Jim Alwood, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8974; email address: [alwood.jim@epa.gov](mailto:alwood.jim@epa.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address:

*TSCA-Hotline@epa.gov.*

## **SUPPLEMENTARY INFORMATION:**

### **I. Executive Summary**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you manufacture (defined by TSCA to include import), process, or use chemical substances subject to regulations in 40 CFR part 721. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers or processors of chemical substances (NAICS codes 325 and 324), e.g., chemical manufacturing, and petroleum and coals manufacturing.

#### *B. What is the Agency's Authority for Taking this Action?*

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Such rules are called “significant new use rules” (SNURs). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)). Section 5(a)(1)(A) of TSCA requires persons to notify EPA at least 90 days before manufacturing a new chemical substance for commercial purposes (under TSCA manufacture includes import). Section 3(9) of TSCA defines a “new chemical substance” as any substance that is not on the TSCA Inventory of Chemical Substances compiled by EPA under section 8(b) of TSCA.

*C. What Action is the Agency Taking?*

EPA is proposing changes to general requirements for SNURs in 40 CFR Part 721, Significant New Uses of Chemical Substances. Most of the proposed changes are changes to the standard significant new uses for new chemical SNURs identified in subpart B which apply to chemical substances when they are cited in subpart E. Other proposed changes are procedural changes to the general provisions in subpart A that apply to all SNURs. EPA is also clarifying in the preamble of this proposed rule some definitions contained in 40 CFR part 721 and proposing a minor change to reporting requirements for TSCA section 5 notices in 40 CFR parts 720.38, 720.45 and 723.50.

*D. Why is the Agency Taking this Action?*

Based on changes that have occurred for respiratory protection requirements since 1989, as codified in NIOSH regulations at 42 CFR part 84 and the OSHA standard at 29 CFR 1910.134, EPA is proposing changes to 40 CFR 721.63. In addition, based on the changes to 29 CFR 1910.1200, OSHA's modified Hazard Communication Standard (HCS) published March 26, 2012 (77 FR 17574) (Ref. 1), EPA is proposing changes to 40 CFR 721.72. EPA is also proposing other changes to 40 CFR part 721 subparts A and B and clarifying definitions contained in 40 CFR part 721. EPA is proposing these changes and making the clarifications based on its experience in issuing and administering over 2,800 SNURs. Many of the proposed changes are based on public comments received by EPA when proposing and issuing SNURs, and questions from the public regarding current SNUR requirements such as: considering a hierarchy of controls before using personal protective equipment to control exposures; clarifying what use other than as described in the premanufacture notice referenced in subpart E of this part for the substance means under 40 CFR 721.80(j);

allowing for removal in wastewater treatment when computing estimated surface water concentrations according to 40 CFR 721.91; and revising the *bona fide* procedure in 40 CFR 721.11 to include coverage of situations where the significant new use terms are confidential.

*E. What are the Estimated Incremental Impacts of this Action?*

There will be a very minor increase in the overall compliance burden and cost because of the modified requirements in 40 CFR parts 720, 721, and 723. The modified SNUR requirements will be compatible with the current hazard communication requirements under 29 CFR 1910.1200 and the respiratory protection requirements at 42 CFR Part 84 and 29 CFR 1910.134. The modified SNUR requirements will also allow persons subject to a SNUR that has been previously issued to use the updated requirements of 40 CFR 721.63 and 721.72 without additional rulemaking.

*F. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

## **II. Background**

On July 27, 1989 (54 FR 31298; FRL-3504-6) (Ref. 2), EPA published a final rule, titled “Significant New Use Rules; General Provisions for New Chemicals Follow-up” that put into place an expedited process for issuing SNURs for certain new chemical substances. The process applies to new chemical substances for which EPA has issued TSCA section 5(e) consent orders and other new chemical substances for which no TSCA section 5(e) consent orders have been issued, but that may present risks to human health or the environment if exposures or releases are significantly different from those described in the PMN. EPA has issued over 2,800 new chemical SNURs using these standard significant new uses. The standard designations in the sections titled “Protection in the workplace” (40 CFR 721.63) and “Hazard communication program” (40 CFR 721.72) were modeled on OSHA and NIOSH regulations that were in force at the time the rule was issued in 1989.

The July 27, 1989 final rule established subparts B, C, and D and amended subpart A of 40 CFR Part 721. Subpart A contains definitions and general provisions that apply to all SNURs. In subpart B of 40 CFR Part 721, EPA identified certain standard significant new uses that EPA regularly cites in new chemical SNURs. For example, EPA may consider use of a specific chemical substance to be a “significant new use” if the use does not meet requirements for protection in the workplace as described in 40 CFR 721.63(a)(1). EPA applies these standard significant new uses as appropriate when promulgating SNURs for a specific chemical substance. As explained in 40 CFR 721.50, these standard significant new use designations apply only when they are referenced as applying to a chemical substance listed in 40 CFR Part 721 subpart E. Subpart C describes recordkeeping requirements for SNURs. As described in 40 CFR 721.100, these standard recordkeeping requirements apply

only when they are referenced as applying to a chemical substance listed in 40 CFR Part 721 subpart E. Subpart D describes an expedited process for issuing significant new use rules for new chemical substances and the process for the modification or revocation of significant new use requirements for new chemical substances. Subpart E lists significant new use and recordkeeping requirements for specific chemical substances.

On March 29, 1995 (60 FR 16311; FRL-4291-9) (Ref. 3), EPA published an amended rule titled, “Amendment for Expedited Process to Issue Significant New Use Rules for Selected New Chemical Substances.” The rule amendment authorized EPA to use “significant new use” designations using expedited rulemaking procedures to promulgate SNURs for certain new chemical substances not subject to TSCA section 5(e) orders (referred to as non-section 5(e) SNURs). The amendment authorized EPA to include other designations, such as protection in the workplace and hazard communication, in non-section 5(e) SNURs promulgated via expedited rulemaking procedures.

As explained in the March 29, 1995 final rule, a TSCA section 5(e) consent order applies only to the original PMN submitter who signs the consent order, while a SNUR applies to all other manufacturers and processors of the chemical substance. The reporting requirements of a non-section 5(e) SNUR apply to all manufacturers and processors of a chemical substance including the PMN submitter. The changes to subpart B in this proposed rule would make it possible for EPA to issue non-section 5(e) SNURs as direct final rules with the updated standard SNUR designations.

How the different subparts of 40 CFR part 721 are used for new chemical SNURs and existing chemical SNURs are summarized in Table 1. New chemical SNURs are issued for certain chemical substances that have undergone PMN review. EPA typically utilizes

subparts B, C, and D when issuing new chemical SNURs. Other SNURs including existing chemical SNURs may be issued for chemical substances either not on the TSCA Inventory or for those on the TSCA Inventory that typically have not undergone PMN review. EPA does not use subpart B or D for existing chemical SNURs but has applied the standard recordkeeping requirements in subpart C. The general requirements of subpart A apply to all SNURs unless they are modified in the significant new use requirements for a specific chemical substance in subpart E. Subpart E lists significant new use and recordkeeping for new and existing chemical substances

**Table 1. Subparts used for New Chemical SNURs and Other Chemical SNURs.**

<b>Regulation</b>	<b>New Chemical SNURs</b>	<b>Other Chemical SNURs</b>
Subpart A. General Provisions (§§721.1 – 721.47)	X	X
Subpart B. Certain Significant New Uses (§§721.50 – 721.91) <ul style="list-style-type: none"> <li>• §721.63. Protection in the Workplace</li> <li>• §721.72. Hazard Communication Program</li> <li>• §721.80. Industrial, Commercial, and Consumer Activities</li> <li>• §721.85. Disposal</li> <li>• §721.90. Release to water</li> <li>• §721.91. Concentration of estimated surface water concentrations: Instructions</li> </ul>	X X X X X X	
Subpart C. Recordkeeping Requirements (§§721.100 – 721.125)	X	X
Subpart D. Expedited Process for issuing Significant New Use Rules for Selected Chemical Substances and Limitation or Revocation of Selected Significant New Use Rules (§§721.160 – 721.185)	X	
Subpart E. Significant New Uses for Specific Chemical Substances (§§721.225 – 721.10829)*	X	X



*revised for each published SNUR.		
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EPA is proposing substantive changes or clarifying language in subparts A and B. The proposed changes in subpart A would affect all SNURs. The proposed changes in Subpart B may affect some previously issued new chemical SNURs already in subpart E and would affect future new chemical SNURs that would be issued using the changed terms in Subpart B. Unit III describes each proposed change and how the changes affect previously issued SNURs and SNURs that would be issued after the proposed rule becomes final. Not all of the more than 2,800 previously issued new chemical SNURs will be affected by the changes in Subpart B. For example, as described in the economic analysis for this proposed rule (Ref.13), per the EPA Chemical Data Report for Reporting Year 2011, 195 chemicals were reported in commerce and subject to new chemical SNURS. Only 60 of the 195 chemicals contained provisions for worker protection and/or hazard communication. This rule does not propose any changes to subparts C, D, or E.

In March, 2012, OSHA modified its Hazard Communication Standard (HCS) to conform to the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS) to enhance the effectiveness of the HCS by ensuring that employees are apprised of the chemical hazards to which they may be exposed, and by reducing the incidence of chemical-related occupational illnesses and injuries. (Ref. 1) The GHS is an internationally harmonized system for classifying chemical hazards and developing labels and safety data sheets. It is a set of criteria and provisions that regulatory authorities can incorporate into existing systems, or use to develop new systems.

The GHS allows a regulatory authority to choose the provisions that are appropriate to its sphere of regulation. This is referred to as the "building block approach." The GHS

includes all of the regulatory components, or building blocks, that might be needed for classification and 22 labeling requirements for chemicals in the workplace, transport, pesticides, and consumer products. The modified HCS adopted those sections of the GHS that are appropriate to OSHA's regulatory sector. For example, while the GHS includes criteria on classifying chemicals for aquatic toxicity, these provisions were not adopted for the HCS because OSHA does not have the regulatory authority to address environmental concerns. The building block approach also gives regulatory agencies the authority to select which classification criteria and provisions to adopt. OSHA adopted the classification criteria and provisions for labels and SDSs, because the current HCS covers these elements. As described in Unit III, EPA is also proposing to adopt some of the GHS criteria for hazard communication pertaining to aquatic toxicity.

### **III. Summary of Proposed Rule**

As a result of changes to OSHA and NIOSH requirements, and other issues identified through EPA's experience issuing and administering SNURs, EPA is proposing several changes to the SNUR regulations in subparts A and B. EPA will describe each proposed change and the reason for proposing the change.

#### *1. Proposed changes to 40 CFR 721.63, Protection in the Workplace.*

Based on changes that have occurred in respiratory protection requirements since 1989, per the NIOSH regulation at 42 CFR part 84 and the OSHA standard at 29 CFR 1910.134, EPA is proposing changes to 40 CFR 721.63. In June 1995, NIOSH updated and modernized its Federal regulation for testing and certifying non-powered, air-purifying, and particulate-filter respirators (42 CFR part 84). The 42 CFR part 84 respirators have passed a more demanding certification test than older respirators (e.g., dust and mist [DM], dust, fume and mist [DFM],

spray paint, pesticide) previously certified under 30 CFR part 11, and provide increased worker protection (Ref. 4). Because the 42 CFR part 84 test criteria simulate worst-case respirator use, NIOSH has encouraged discontinuing the use of particulate respirators certified under 30 CFR part 11 and switching to particulate respirators certified under 42 CFR part 84. However, non-powered particulate respirators that were approved under 30 CFR part 11 using the “old” labeling were allowed to be manufactured and sold until July 10, 1998. Specifically, distributors who purchased 30 CFR part 11 particulate filters and respirators prior to July 10, 1998, are able to sell them as "certified" until inventories of these products are depleted. Users who purchased such particulate filters and respirators from these distributors will be able to use them until their inventories are depleted or until the end of the shelf life or service life for these products.

Additionally, in January 1998, OSHA's revised Respiratory Protection Standard (29 CFR 1910.134) replaced the respiratory protection standards adopted by OSHA in 1971 (Ref. 5). Subsequently, in August 2006, OSHA announced that it modified its Respiratory Protection Standard (29 CFR 1910.134) by adding definitions as well as maximum use concentration (MUC) and assigned protection factor (APF) requirements to 29 CFR 1910.134 (Ref. 6). Due to these changes, the respirators currently listed in 40 CFR 721.63 may no longer meet the current NIOSH/OSHA criteria for respirator selection and use.

EPA is proposing to update language pertaining to respiratory protection requirements that is listed in 40 CFR 721.63(a)(4), (a)(5), and (a)(6) to be consistent with both OSHA and NIOSH requirements. In 40 CFR 721.63(a)(4) which requires that respirators be used in accordance with 30 CFR part 11, EPA is proposing to replace the reference to 30 CFR part 11 with a reference to 42 CFR part 84 to cite the most updated

NIOSH regulation for testing and certifying respirators. Most manufacturers and processors are already subject to and complying with 42 CFR part 84. This change would apply to all previously issued SNURs that contain significant new use requirements pertaining to respiratory protection in that it will make clear that manufacturers and processors subject to current SNURs can follow updated respiratory protection requirements without triggering a SNUN requirement; and the updated language would be cited when issuing new SNURs as appropriate. EPA is proposing updated NIOSH-certified respirator language in 40 CFR 721.63(a)(5). EPA is currently citing the new respirator language in SNURs and has not been referencing the respirators currently listed in 40 CFR 721.63(a)(5). EPA intends to continue citing the new respirator language when issuing new SNURs during the pendency of this rulemaking. The proposed updates to 40 CFR 721.63(a)(5) would standardize the use of the new respirator language by allowing EPA to cross-reference the respirator language for new chemical SNURs rather than impose the respirator language on a case-by-case basis.

EPA is proposing language that would allow persons subject to SNURs with older respirator requirements in 40 CFR 721.63(a)(5) already cited in subpart E to avoid triggering a SNUN requirement by continuing to use those respirators, if they are available. These are the 15 listed respirators in 40 CFR 721.63(a)(5)(i) through (xv). EPA is also proposing language in 40 CFR 721.63(a)(5) that would allow persons subject to the older respirator requirements in 40 CFR 721.63(a)(5)(i) through (xv) to use an equivalent respirator under the newer requirements provided that the APF of the new respirator is equal to or greater than the respirator cited in subpart E. EPA has included in the public docket a chart comparing the APF of the respirator classes in the current regulations with the corresponding older respirator requirements that can be consulted in order to determine availability of suitable

substitutes (Ref. 7). The proposed language in 40 CFR 721.63(a)(6) also updates language for the airborne form of a chemical substance that would apply to the respiratory protection requirements in 40 CFR 721.63(a)(4). EPA would cite this language when issuing new SNURs.

Any personal protection equipment requirements would be a minimum set of requirements so that users are encouraged to modernize (upgrade to next generation) protective equipment to include such features as an electronic chip to identify when personnel use and discontinue use of a respirator. The electronic chip also could monitor the condition and maintenance of the respirator. EPA is specifically requesting comments on the use of next generation respirators.

EPA is also proposing a revision to 40 CFR 721.63 that would make it a significant new use not to implement a hierarchy of controls to protect workers. This revision would require persons subject to applicable SNURs to determine and use appropriate engineering and administrative controls before using personal protective equipment (PPE) for worker protection, similar to the requirements in OSHA standards at 29 CFR 1910.134(a)(1) and guidance in Appendix B to subpart I of 29 CFR 1910.

This change is being proposed partly due to comments received on recently promulgated SNURs. In response to the proposed SNURs published in the **Federal Register** of December 28, 2011 (76 FR 81447) (FRL-9326-2) (Ref. 8), EPA received comments from 26 public submissions. Each of these comments generally stated that EPA's approach of exclusively identifying the absence of adequate personal protective equipment as a significant new use instead of engineering and administrative controls is not following the best occupational health and safety practices. The commenters suggested approaches that

EPA could adopt. Several commenters identified the industrial hygiene “hierarchy of controls” approach for workplace health and safety, where elimination, substitution, engineering controls, and workplace or administrative controls should be implemented before use of personal protective equipment for worker protection. Several commenters stated that persons subject to SNURs should follow the OSHA requirements to use controls that are higher in the hierarchy of controls before requiring employees to use personal protective equipment. Some commenters suggested that EPA should specifically incorporate the OSHA requirements at 29 CFR 1910.134(a)(1) into each SNUR or modify standard requirements for SNURs at 40 CFR 721.63 to require a hierarchy of controls. Other commenters noted several publications or standards that either specifically recommend a hierarchy of controls or recommend an approach using engineering controls to prevent exposures before using personal protective equipment.

In the final SNURs published on June 26, 2013 (78 FR 32810)(FRL-9390-6) (Ref. 9), EPA responded to the comments, agreeing that a hierarchy of controls should be applied and that PPE should be the last option to control exposures. EPA noted that its New Chemicals Exposure Limits language in TSCA section 5(e) consent orders already states that attempting to prevent exposures through higher controls in the hierarchy than PPE is EPA’s preferred method for protecting workers. See: [http://www.epa.gov/sites/production/files/2015-06/documents/draft\\_ncel\\_insert\\_042115.pdf](http://www.epa.gov/sites/production/files/2015-06/documents/draft_ncel_insert_042115.pdf) (Ref. 10). EPA added language to the final SNURs issued June 26, 2013, that contained significant new uses pertaining to PPE for workers to require persons subject to the SNURs to consider and implement engineering controls and administrative controls where feasible. Where engineering and administrative

controls are not feasible or are insufficient to protect exposed workers, persons who are subject to a SNUR must follow any PPE requirements or submit a SNUN to EPA.

All new chemical SNURs published since June 26, 2013 have included the same language to consider and implement engineering controls and administrative controls where feasible when the SNURs contained significant new uses pertaining to the lack of PPE for workers. These requirements to consider engineering and administrative controls are based on and consistent with the OSHA requirements at 29 CFR 1910.134(a)(1). EPA is proposing to revise 40 CFR 721.63(a)(1) and 40 CFR 721.63(a)(4) to add language which requires consideration and use of engineering and administrative controls where feasible before PPE for worker protection. This proposed change would affect SNURs issued after this proposed rule becomes a final effective rule and would affect previously issued SNURs that incorporate worker protection referencing the existing 40 CFR 721.63(a)(1) and 40 CFR 721.63(a)(4) regulations. EPA believes most companies are already following a hierarchy of controls due to OSHA regulations. EPA is specifically seeking comments on this proposal to incorporate a hierarchy of controls for significant new use rules.

*2. Proposed changes to 40 CFR 721.72, Hazard Communication Program.*

Based on the changes to 29 CFR 1910.1200, OSHA's modified HCS, EPA is proposing changes to 40 CFR 721.72. In March, 2012, OSHA modified its HCS to conform to the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS) to enhance the effectiveness of the HCS by ensuring that employees are apprised of the chemical hazards to which they may be exposed, and by reducing the incidence of chemical-related occupational illnesses and injuries. (Ref. 1) Modifications to the HCS include revised criteria for classification of chemical hazards; revised labeling

provisions that include requirements for use of standardized signal words, pictograms, hazard statements, and precautionary statements; a specified format for safety data sheets; and related revisions to definitions of terms used in the HCS and requirements for employee training on labels and safety data sheets.

Under the current rules, when SNURs are issued citing section 40 CFR 721.72 in subpart E for a chemical substance, it is considered a significant new use if the company does not develop a written hazard communication program for the substance in the workplace. Paragraphs (a) through (h) of 40 CFR 721.72 can be cited in subpart E as the elements that must be included in the hazard communication program. Manufacturers and processors subject to a SNUR in subpart E for a chemical substance can rely on an existing hazard communication program, such as one established under the OSHA HCS or one based on GHS recommendations to comply with this significant new use requirement to the extent the hazard communication program contains elements cited for that SNUR from 40 CFR 721.72 paragraphs (a) through (h).

EPA is proposing to add new paragraphs (i) and (j) that EPA would use when issuing hazard communication requirements for SNURs issued after this rulemaking has been finalized. The new paragraph (i) would require that a written hazard communication program be developed and implemented for the substance in each workplace in accordance with 29 CFR 1910.1200, the OSHA HCS.

The proposed approach would maintain consistency in compliance for persons subject to TSCA and OSHA regulations for the same activity. Because the OSHA HCS is detailed and complex, by cross-referencing it EPA would avoid any errors in duplication as well as avoid the unintentional creation of additional obligations. In addition, any amendments to the



OSHA HCS would apply at the same time for the purposes of complying with the SNUR. This approach would also be consistent with the requirement for EPA to coordinate with other federal executive departments and agencies under TSCA section 9(d) to impose “the least burdens of duplicative requirements on those subject to the chapter and for other purposes.”

The new paragraph (j) describes specific statements and other warnings that could be required for SNURs for substances identified in subpart E. The specific statements and warnings that could be required would be based on EPA’s risk assessment of the chemical substance and would be consistent with the OSHA HCS and GHS recommendations.

EPA expects that, whenever the statements in paragraphs (g), (h), and (j) are required and the determinations for the SNUR are published, manufacturers and processors subject to the SNUR will also consider if they trigger any other corresponding hazard communication requirements under the OSHA HCS or recommendations under GHS recommendations. Any hazard and precautionary statements required by the SNUR would be a minimum set of hazard warnings. EPA may also propose individual SNURs or issue section 5(e) SNURs under 40 CFR 721.160 using other specific statements, signal words, symbols, hazard category, and pictograms as hazard communication requirements.

EPA is proposing to update 40 CFR 721.72 paragraphs (a) through (h) to be consistent with both OSHA requirements and GHS recommendations. When the rulemaking is finalized, these changes would apply to individual SNURs in subpart E issued before the effective date of the final rule as described in the next two paragraphs. EPA is proposing changes to 40 CFR 721.72 paragraphs (a), (c), and (d) to change using the word material safety data sheet (MSDS) to safety data sheet (SDS) and to allow easily accessible electronic

versions and other alternatives to maintaining paper copies of the SDS. These changes would apply to any previously issued SNUR in subpart E that cites these paragraphs. EPA is also proposing changes pertaining to hazard and precautionary statements that are listed in 40 CFR 721.72 paragraphs (g) and (h) to be consistent with statements required under the OSHA HCS and recommended by the GHS. The proposed changes would add new precautionary and hazard statements that are consistent with the OSHA HCS and GHS recommendations. While the previously issued SNUR precautionary and hazard statements will be retained solely for previously issued SNURs, EPA is proposing to identify which of the proposed new statements can be used as alternatives. EPA is proposing that manufacturers and processors subject to a previously issued SNUR will have the option to use the prior older precautionary and hazard statements or use the new alternative statements that are consistent with the OSHA HCS or GHS recommendations to comply with the SNUR.

EPA is also proposing language allowing any person subject to a previously issued SNUR for a substance identified in subpart E containing requirements for 40 CFR 721.72 paragraphs (a) through (h) to comply with those requirements by following the requirements of the proposed 40 CFR 721.72 paragraph (i), which is being proposed for use in future SNURs, and using any statements specified for that substance in the proposed 40 CFR 721.72 paragraphs (g) or (h). For example, a person currently subject to a SNUR citing the requirements to establish a hazard communication program as described in 40 CFR part 721.72 paragraphs (a) through (f) and the requirement for a hazard statement in paragraph (g)(1)(iii), central nervous system effects, could comply by taking the following steps: That person could establish a hazard communication program according to the requirements in the

proposed paragraph (i) and use the hazard statement in paragraph (g)(1)(iii), “central nervous system effects,” or the proposed alternative hazard statement (g)(1)(xi), “may cause damage to the central nervous system through prolonged or repeated exposure.”

EPA recommends using a Chemical Abstracts Service (CAS) number to identify the chemical substance whenever available. EPA makes this recommendation because CAS numbers are widely used by industry including in SDSs to provide a unique identifier for chemical substances and provide an unambiguous way to identify a chemical substance, unlike the variety of possible systematic, generic, or proprietary names that may be available for the same chemical substance. Only when a CAS number is not available should a different unique numerical identifier be used. Because of variations in naming conventions for chemical substances, using CAS numbers makes it easier for the regulated community to accurately identify and report chemical identities. For example, upon importation of a chemical substance, if the chemical substance is being identified to assure compliance with regulatory requirements, providing the most specific CAS number is the most efficient and clear way to ensure this. The proposed changes for SNUR hazard communications requirements concerning how to identify chemical substances would be consistent with OSHA regulations.

*3. Clarification of the use of 40 CFR 721.80, Industrial Commercial and Consumer Activities.*

EPA is also clarifying its use of the significant new use for new chemical SNURs described at 40 CFR 721.80(j), which identifies as a significant new use, “Use other than as described in the premanufacture notice referenced in subpart E of this part for the substance.” EPA is not proposing to change the language of 721.80(j). Instead, EPA is clarifying how it

identifies as a significant new use, “Use other than as described in the premanufacture notice referenced in subpart E of this part for the substance” for individual SNURs. When EPA issues a SNUR using the designation at 40 CFR 721.80(j) in subpart E for a chemical substance and that use described in the premanufacture notice is claimed as confidential, EPA cites 40 CFR 721.80(j). See Unit III.5 for a discussion of how manufacturers and processors subject to a SNUR with a confidential significant new use designation can currently file a *bona fide* inquiry to determine whether a specific use is a significant new use and EPA’s proposal for future *bona fide* inquiries. In identifying the significant new use in subpart E for certain previously issued SNURs where the use described in the premanufacture notice was not claimed confidential, EPA cited 40 CFR 721.80(j) and included the PMN use described in the premanufacture notice in parentheses. EPA has received public comments in response to proposed SNURs and pre-notice inquiries for SNURs that manufacturers and processors subject to SNURs find it confusing when EPA cites 40 CFR 721.80(j) and then identifies the PMN use in parentheses. These comments and inquiries have stated that when EPA cites the new use this way it appears as though the significant new use is the use in the parentheses, where the significant new use is actually use other than the use in parentheses given 40 CFR 721.80(j).

To more clearly identify the significant new use, EPA has changed this procedure to only cite 40 CFR 721.80(j) when the use described in the PMN is confidential. When the use described in the PMN is not confidential, EPA intends to identify the significant new use in a new chemical SNUR by describing the use, such as in the following example: “A significant new use is any use other than as a pesticide intermediate.” (This example was published in

the direct final SNUR issued on February 12, 2014 (79 FR 8291) (Ref. 11) and is codified in subpart E at 40 CFR 721.10718.)

*4. Proposed changes to 40 CFR 721.91, Computation of estimated surface water concentrations: Instructions.*

When EPA issues a new chemical SNUR citing the significant new uses described in 40 CFR 721.90 (a)(4), (b)(4), and (c)(4), the SNUR requires significant new use notification if the results of the equation for computation of estimated surface water concentrations in 40 CFR 721.91 exceed the level specified for that SNUR in subpart E. The equation estimates surface water concentrations based on the amount of a chemical substance released from industrial processes and the flows of the water body. The current equation does not take into consideration amounts of a chemical substance released to a surface water after control technology such as wastewater treatment. EPA is proposing to revise this requirement to allow manufacturers and processors to account for reductions in surface water concentrations resulting from wastewater treatment. 40 CFR 721.91 contains instructions for the computation of estimated surface water concentrations according to the equation specified in 40 CFR 721.90 (a)(4), (b)(4), and (c)(4). EPA is proposing to revise 40 CFR 721.91 to allow for a certain percentage of removal of a chemical substance from wastewater when undergoing control technology, when using the equation to calculate surface water concentrations to meet requirements in 40 CFR 721.90. EPA has previously allowed surface water concentrations to be calculated with a consideration of wastewater treatment in certain SNURs by adding regulatory text to individual rules. This change to 40 CFR 721.91 will make the consideration of control technology part of the calculations for the equation specified in 40 CFR 721.90 when cited in subpart E for a specific chemical substance. EPA

will cite the control technology and the percentage removal for SNURs in subpart E, based on EPA's assessment of the effectiveness of the control technology for the specific chemical substance. Based on past experience with new chemical SNURs, EPA expects that the control technology will usually be wastewater treatment. However, EPA will not identify a percentage of removal from wastewater for every chemical substance subject to a SNUR with the significant new use specified in 40 CFR 721.90 (a)(4), (b)(4), and (c)(4). EPA would identify an applicable removal percentage when issuing new SNURs. It does not apply to existing SNURs where a removal percentage has not been identified.

Because of numerous questions from manufacturers and processors about the phrase "predictable or purposeful release" in 40 CFR 721.90, EPA is clarifying the meaning of that phrase. The phrase is used to qualify significant new uses pertaining to releases to water in 40 CFR 721.90. As described in the proposed rule of April 29, 1987, Proposed General Provisions for New Chemicals Follow-up (52 FR 15608) (Ref. 12), the phrase predictable or purposeful does not include releases where true emergency conditions exist and significant new use notification is not possible. Therefore, routine or repeated activity that results in releases to water or non-routine releases to water that are not due to emergency conditions would be included in the term predictable or purposeful. EPA did not intend the phrase "predictable or purposeful release" to limit the agency's strict liability authority under the statute.

*5. Proposed changes to 40 CFR 721.11, Determining whether a chemical substance or a specific use is subject to this part when the chemical substance identity or significant new use is confidential.*

Some new chemical SNURs have a significant new use designation which is a

production volume limit or use other than described in the PMN that is based on CBI contained in the PMN and which is therefore not disclosed in the published SNUR.

Currently, for each SNUR that contains a significant new use designation that is CBI, that SNUR cross-references the *bona fide* procedure in the specific SNUR in subpart E for 40 CFR 721.1725. That specific SNUR contains a significant new use designation that includes CBI (and is therefore not disclosed in the published SNUR) and describes the *bona fide* procedure that must be followed to allow a person to determine whether a specific use is a significant new use.

When the chemical identity in a SNUR is CBI, 40 CFR 721.11 provides a means by which *bona fide* submitters can determine whether their substance is subject to the SNUR. However, as described in the previous paragraph, chemical identity is not the only information contained in a SNUR that may be claimed as CBI. EPA is proposing to modify the *bona fide* procedure in 40 CFR 721.11 of subpart A of 40 CFR part 721 so that it applies to all SNURs that contain any confidential information in the SNUR, including the significant new use. EPA believes it would be more efficient to have a *bona fide* procedure for determining confidential significant new uses in subpart A rather than referencing 40 CFR 721.1725(b)(1) each time EPA issues a SNUR containing a confidential significant new use designation. In addition, EPA is proposing to modify the *bona fide* procedure that allows EPA to disclose the confidential significant new use designations to a manufacturer or processor who has established a *bona fide* intent to manufacture (including import) or process a particular chemical substance.

*6. Proposed changes for submission of SDS(s) with PMNs, SNUNs, Low Volume Exemptions (LVEs), Low Release and Exposure Exemptions (LoREXs), and Test Marketing*

*Exemption (TME) Applications.*

EPA is proposing to revise requirements in 40 CFR 720.38, 720.45, and 40 CFR 723.50 to require that any SDS already developed to either comply with OSHA requirements or already developed by a notice submitter for other purposes must also be submitted as part of the notification (PMN, SNUN, LVE, LoREX, or TME application) under section 5 of TSCA. Many submitters already submit available SDSs as part of their submission and the information contained in SDSs is often useful for EPA's assessments of chemicals. This proposed revision would not require submitters to develop an SDS. It would only require a submitter to submit an SDS that has already been developed to the extent it is known or reasonably ascertainable by the submitter.

*7. Fixing typographical errors and other non-substantive changes.*

EPA is proposing to correct several typographical errors and more accurately use the terms manufacture, manufacturer, and manufacturing in the regulatory text of sections 40 CFR parts 720, 721, and 723.

**IV. Economic Analysis**

EPA evaluated the potential costs of implementing these proposed changes to section 5 SNUR requirements for potential manufacturers (including importers) and processors of the chemical substances. The proposed changes result in minimal increases in burden associated with issuing future SNURs and administration and compliance with previously issued SNURs. For new chemical SNURs, the incremental increase is estimated at 364 hours of burden with an associated \$20,387 in the steady state; for section 5 notices, the incremental increase is estimated at 247 hours of burden with an associated cost of \$17,843 in the steady state. The Agency's complete Economic Analysis is available in the docket



under docket ID number EPA–HQ–OPPT–2014-0650 (Ref. 13).

## V. References

The following is a listing of the documents that are specifically referenced in this action. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. 2012. OSHA. OSHA Revised Hazard Communication Standard; Final Rule. **Federal Register** (77 FR 17574, March 26, 2012).
2. 1989. EPA. Significant New Use Rules; General Provisions for New Chemicals Follow-up; Final Rule. **Federal Register** (54 FR 31298, July 27, 1989)(FRL-3504-6).
3. 1995. EPA. Amendment for Expedited Process to Issue Significant New Use Rules for Selected New Chemical Substances; Final Rule. **Federal Register** March 29, 1995 (60 FR 16311, March 29, 1995)(FRL-4291-9).
4. 1995. NIOSH. Respiratory Protection Devices; Final Rule. **Federal Register** (60 FR 30355, June 8, 1995).
5. 1998. OSHA. Respiratory Protection; Final Rule. **Federal Register** (63 FR 1152, January 8, 1998).
6. 2006. OSHA. Assigned Protection Factors; Final Rule. **Federal Register** (71 FR 50121, August 24, 2006).
7. 2015. EPA. Chart comparing assigned protection factors of current respirator classes with older respirator requirements.

8. 2011. EPA. Proposed Significant New Use Rules on Certain Chemical Substances; Proposed Rule. **Federal Register** (76 FR 81447, December 28, 2011)(FRL-9326-2).
9. 2013. EPA. Significant New Use Rules on Certain Chemical Substances; Final Rule. **Federal Register** (78 FR 32810, June 26, 2014)(FRL-9390-6).
10. 2015. EPA. Boilerplate consent order containing new chemicals exposure limits. [http://www.epa.gov/sites/production/files/2015-06/documents/draft\\_ncel\\_042115.pdf](http://www.epa.gov/sites/production/files/2015-06/documents/draft_ncel_042115.pdf).
11. 2014. EPA. Significant New Use Rules on Certain Chemical Substances; Direct Final Rule. **Federal Register** (79 FR 8291, February 12, 2014) (FRL- 9903-70).
12. 1987. EPA. Significant New Uses of Chemical Substances; General Provisions for New Chemical Follow-up; Proposed Rule. **Federal Register** April 29, 1987 (52 FR 15594, April 29, 1987)(FRL-3153-6).
13. 2016. EPA. Economic Analysis for Proposed Rule Amendments to Part 721 – Modifications to General and Specific Requirements in the SNUR Framework – Significant New Uses of Chemical Substances. (RIN 2070-AB27). March 2016..

## **VI. Statutory and Executive Order Reviews**

### *A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

The Office of Management and Budget (OMB) has determined that this proposed rule is not a “significant regulatory action,” under section 3(f) of Executive Order 12866 (58 FR 51735, October 4, 1993). Accordingly, this action was not submitted to OMB for review under Executive Order 12866 and 13563 (76 FR 3821, January 21, 2011).

### *B. Paperwork Reduction Act (PRA)*

An agency may not conduct or sponsor, and a person is not required to respond to an information collection request subject to the PRA (44 U.S.C. 3501 *et seq.*), unless it displays a currently valid OMB control number. The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574.15). This action would not impose any burden requiring additional OMB approval. Estimates presented below reflect incremental changes associated with the rule.

***Respondents/affected entities:*** *Certain manufacturers (including importers) and processors.*

Description	Number of Respondents	Number of Responses
Section 5 Notices	988	988
New Chemical SNURs (newly issued and previously issued)	221	334
Rule Total	1,209	1,322

***Respondent's obligation to respond:*** *Mandatory*

***Frequency of Response:*** *Incidental, upon submission of notice or implementing/updating New Chemical SNURs.*

***Total estimated incremental burden (hours per year):*** Burden is defined at 5 CFR part 178.

Description	First Year	Steady State
Section 5 Notices	415	247
New Chemical SNURs (newly issued and previously issued)	661	364
Rule Total	1,073	611

***Total estimated incremental cost (2014\$ annual):***

Description	First Year	Steady State
Section 5 Notices	\$30,420	\$17,843
New Chemical SNURs (newly issued and previously issued)	\$42,618	\$20,386
Rule Total	\$73,038	\$38,229

In your comments on this proposed rule, EPA is also interested in any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including revisions to the automated collection techniques being used for submissions to EPA under TSCA, which are now required to use the Agency's Central Data Exchange (CDX) portal at [http://cdx.epa.gov/epa\\_home.asp](http://cdx.epa.gov/epa_home.asp).

### *C. Regulatory Flexibility Act (RFA)*

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), I hereby certify that this action would not have a significant adverse economic impact on a substantial number of small entities. The Agency's basis is briefly summarized here and is detailed in the economic analysis in the public docket for this proposed rule (Ref. 13).

Under the RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this proposed rule on small entities, small entity is defined as: (1) a small business, as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. Since the regulated community is not expected to include small governmental jurisdictions or small not-for-profit organizations, the analysis focuses on small businesses.

EPA has observed only a very small proportion of SNUNs submitted by self-declared small businesses. To the extent that the percentage of small firms abiding by a SNUR is similar to the percentage of small firms submitting SNUNs, it is unlikely that a substantial

number of small entities would be affected by this proposed rule's changes to SNUR requirements. Similarly, for section 5 notices, assuming that a similar small proportion of small firms are submitting all notices, it is likewise unlikely that substantial number of small entities would be affected by this proposed rule's changes.

EPA also believes the incremental per-response costs for complying with the proposed rule at \$61 per SNUR chemical•firm and \$18 per notice are low compared to the cost of developing and marketing a chemical new to the firm. Given the relatively low prevalence of small businesses in the new chemicals universe, and the extremely small incremental burden, the proposed rule is thus very unlikely to have a significant adverse economic impact on a substantial number of small entities (SISNOSE). Therefore EPA presumes a “no SISNOSE” finding.

EPA continues to be interested in the potential impacts of this proposed rule on small entities and welcomes comments on issues related to such impacts.

#### *D. Unfunded Mandates Reform Act (UMRA)*

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government would be impacted by this rulemaking. As such, EPA has determined that this action would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

#### *E. Executive Order 13132: Federalism*

This action would not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and

responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

*F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175 (65 FR 67249, November 9, 2000), do not apply to this proposed rule.

*G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

*H. Executive Order 13211: Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use*

This action is not a “significant energy Action” as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on energy supply, distribution, or use.

*I. National Technology Transfer and Advancement Act (NTTAA)*

Since this action does not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note) does not apply to this action.

*J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994), because EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations.

**List of Subjects in 40 CFR Parts 720, 721, and 723**

Environmental protection, Chemicals, Hazardous materials, Recordkeeping, and Reporting Requirements.

Dated: June 9, 2016.

Wendy Cleland-Hamnett,

*Director, Office of Pollution Prevention and Toxics.*



Therefore, it is proposed that 40 CFR chapter I be amended as follows:

**PART 720--[AMENDED]**

1. The authority citation for part 720 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2613.

2. In § 720.1, remove the phrase “and importers”.

3. Amend § 720.3 by:

- a. Revising paragraph (r) introductory text.
- b. Revising paragraph (r)(1).
- c. Revising paragraph (s) introductory text.
- d. Revising paragraph (s)(2).
- e. Revising paragraph (cc).

The revisions reads as follows:

**§ 720.3 Definitions.**

\* \* \*

(r) *Manufacture for commercial purposes* means:

(1) To manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, and includes, among other things,

“manufacture” of any amount of a chemical substance or mixture:

\* \* \*

(s) *Manufacture solely for export* means to manufacture for commercial purposes a chemical substance solely for export from the United States under the following restrictions on activities in the United States:

\* \* \*

(2) The manufacturer and any person to whom the substance is distributed for purposes of export or processing solely for export (as defined in §721.3 of this chapter), may not use the substance except in small quantities solely for research and development in accordance with §720.36.

\* \* \*

(cc) *Small quantities solely for research and development* (or “small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product”) means quantities of a chemical substance manufactured or processed or proposed to be manufactured or processed solely for research and development that are not greater than reasonably necessary for such purposes.

\* \* \* \* \*

4. In § 720.25 removing the phrase “or import” wherever it appears in the section.

5. Amend § 720.30 by:

- a. Removing the phrase “or imported” wherever it appears in the section.
- b. Removing in paragraph (h)(7) the word “intended” and add in its place “intended”.

6. In § 720.36 removing the phrases “or imported”, “or importer”, “or imports”

wherever they appear in the section.

7. Amend § 720.38 by:

- a. Removing the phrase “or import” wherever it appears in the section.
- b. Adding paragraph (b)(6) to read as follows:

#### **§ 720.38 Exemptions for test marketing.**

\* \* \*

(b)(6) Any safety data sheet already developed for the chemical substance.

\* \* \* \*

8. In § 720.40, removing the phrases “or import” and “or importer” wherever they appear in the section.

9. Amend § 720.45 by:

a. Removing in paragraph (e), the phrase “or imported” wherever it appears in the paragraph.

b. Adding paragraph (i) to read as follows:

**§ 720.45 Information that must be included in the notice form.**

\* \* \*

(i) Any safety data sheet already developed for the new chemical substance.

\* \* \* \*

10. Removing in § 720.57 paragraph (a), the word “chemcial” and add in its place “chemical”.

11. In § 720.75 paragraph (e)(2), remove the phrase “or importer”.

12. Amend § 720.78 by:

a. Removing in paragraph (b)(1), the phrase “or import”.

b. Removing in paragraph (b)(1)(iv), the word “manufacturer” and add in its place “manufacturer”.

c. Removing in paragraph (b)(2), the phrase “or imports” wherever it appears in the paragraph.

d. Removing in paragraph (c) the phrase “or import”.

13. Amend § 720.85 by:

- a. Removing the phrase “or import” wherever it appears in the section.
- b. Removing the phrase “or importing” wherever it appears in the section.
- c. Removing in paragraph (b)(1) the phrase “or imported”.
- d. Removing in paragraph (b)(1) the word “indentity” and add in its place “identity”.
- e. Removing in paragraph (b)(2)(i) the word “manufactures” and add in its place “manufactures”.
- f. Removing in paragraph (b)(2)(i) the phrase “or imports”.
- g. Removing in paragraph (b)(3)(iv)(D) the phrase “on imported”.
- 14. Removing throughout § 720.90 the phrase “or import” wherever it appears in the section.
- 15. Removing throughout subpart F the phrase “or import” wherever it appears in the subpart.
- 16. Amend § 720.120 by:
  - a. Removing in paragraph (b) the phrase “or imports”.
  - b. Removing in paragraph (b) the word “requied” and add in its place “required”.

**PART 721--[AMENDED]**

- 17. The authority citation for part 721 continues to read as follows:
 

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).
- 18. Removing in part 721, the acronym “MSDS” and add in its place the acronym “SDS” everywhere it appears.
- 19. Removing in part 721, the acronym “MSDSs” and add in its place the acronym “SDSs” everywhere it appears.
- 20. Removing in part 721, the phrase “material safety” and add in its place the word

“safety” everywhere it appears.

21. Removing in § 721.1(a) the phrase “manufacturers, importers and processors” and add in its place “manufacturers and processors”.

22. Amend § 721.3 by:

a. Adding in alphabetical order the definition for “Safety Data Sheet”

b. Revising the definition for “Customer”.

c. Revising the definition of “Employer”.

d. Removing the definition of “MSDS”.

e. Revising the definition of “Non-industrial use”

f. Revising the definition of “Recipient”.

The revisions read as follows:

*Customer* means any person to whom a manufacturer or processor distributes any quantity of a chemical substance, or of a mixture containing the chemical substance, whether or not a sale is involved.

*Employer* means any manufacturer, processor, or user of chemical substances or mixtures.

*Non-industrial use* means use other than at a facility where chemical substances or mixtures are manufactured or processed. *Recipient* means any person who purchases or otherwise obtains a chemical substance directly from a person who manufactures or processes the substance.

*Safety Data Sheet (SDS)* means written or printed material concerning a hazardous chemical substance that is prepared as required under § 721.72(c).

23. Amend § 721.5 by:

a. Removing the phrase “manufacturer, importer, or processor” and add in its place the phrase “manufacturer or processor” everywhere it appears.

b. Removing the phrase “manufacture, import, or process” and add in its place the phrase “manufacture or process” everywhere it appears.

c. Removing in paragraph (d)(1)(iii), the word “recepient’s” and add in its place “recipient’s”.

24. Amend § 721.11 by:

a. Removing the phrase “manufacturer, importer, or processor” and add in its place the phrase “manufacturer or processor” everywhere it appears.

b. Removing the phrase “manufacture, import, or process” and add in its place the phrase “manufacture or process” everywhere it appears.

c. Revising the section heading, and paragraphs (a), (e), (f), and (g).

The revisions reads as follows:

**§ 721.11 Determining whether a chemical substance or a specific use is subject to this part when the chemical substance identity or significant new use is confidential.**

(a) A person who intends to manufacture or process a chemical substance which is subject to a significant new use rule in subpart E of this part may ask EPA whether the substance or a proposed use is subject to the requirements of this part if that substance is

described by a generic chemical name or if the significant new use is confidential and therefore not described specifically in the rule. EPA will answer such an inquiry only if EPA determines that the person has a *bona fide* intent to manufacture or process the chemical substance for commercial purposes.

\* \* \*

(e) If the manufacturer or processor has shown a *bona fide* intent to manufacture or process the substance and has provided sufficient unambiguous chemical identity information to enable EPA to make a conclusive determination as to the identity of the substance, EPA will inform the manufacturer or processor whether the chemical substance is subject to this part and, if so, which section in subpart E of this part applies, and identify any confidential significant new use designations.

(f) A disclosure to a person with a *bona fide* intent to manufacture or process a particular chemical substance that the substance is subject to this part or of confidential significant new use designations will not be considered public disclosure of confidential business information under section 14 of the Act.

(g) EPA will answer an inquiry on whether a particular chemical substance is subject to this part or identify and confidential significant new uses within 30 days after receipt of a complete submission under paragraph (b) of this section.

25. Amend § 721.25 by:

a. Removing in paragraph (a) the phrase “manufacture, import, or processing” and add in its place the phrase “manufacture or processing”.

b. Removing in paragraph (d) the phrase “manufacture, import, or process” and add in its place the phrase “manufacture or process”.

26. Amend § 721.30 by:

- a. Removing the phrase “manufacture, import, or processing” and add in its place the phrase “manufacture or processing” everywhere it appears.
- b. Removing in paragraph (a) the phrase “manufacture, import, or process” and add in its place the phrase “manufacture or process”.

27. Amend § 721.35 by:

- a. Remove the phrase “manufactured, imported, or processed” and add in its place the phrase “manufactured or processed” everywhere it appears.
- b. Removing in paragraph (f)(1) the phrase “manufacture, import, or processing” and add in its place the phrase “manufacture or processing”.

28. Throughout § 721.45 remove the phrase “manufactures, imports, or processes” and add in its place the phrase “manufactures or processes” everywhere it appears.

29. Revise § 721.47 by:

- a. Removing the phrase “manufactures, imports, or processes” and add in its place the phrase “manufactures or processes” everywhere it appears.
- b. Removing the phrase “manufacturer, importer, or processor” and add in its place the phrase “manufacturer or processor” everywhere it appears.
- c. Removing the phrase “manufacture, import, or process” and add in its place the phrase “manufacture or process” everywhere it appears.

30. Amend § 721.63 by:

- a. Revising paragraph (a) introductory text, paragraph (a)(1), (4), and (5)
- b. Adding new paragraphs (a)(5)(xvi) through (a)(5)(li).
- c. Revising paragraph (a)(6).



d. Adding new paragraphs (a)(6)(vii) through (a)(6)(ix).

e. Removing in paragraph (c)(2) the phrase “manufacturer, importer, or processor” and add in its place the phrase “manufacturer or processor”.

The revisions and additions read as follows:

**§ 721.63 - Protection in the workplace**

(a) Whenever a substance is identified in subpart E of this part as being subject to this section, any manner or method of manufacturing (including importing) or processing associated with any use of the substance is considered a significant new use unless a program is established whereby:

(1) Where people are reasonably likely to have dermal or eye exposure to the chemical substance in the work area, either through direct handling of the substance, or through contact with surfaces on which the substance may exist, or because the substance becomes airborne in the form listed in paragraph (a)(6) of this section, and the form is cited in subpart E of this part for the chemical substance, engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. Where engineering, work practice, and administrative controls are not feasible or dermal or eye exposure is still reasonably likely, each person who is reasonably likely to be exposed to the chemical substance by dermal or eye exposure must be provided with, and is required to wear, personal protective equipment (PPE) to prevent dermal or eye exposure to the substance. Refer to 29 CFR 1910.132 and 29 CFR 1910.133 for requirements on selection and use of PPE.

\* \* \*

(4) Where each person who is reasonably likely to be exposed to the chemical substance by inhalation in the work area in one or more of the forms listed in paragraph (a)(6) of this section and cited in subpart E of this part for the chemical substance, engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. When engineering, work practice, and administrative controls are not feasible or inhalation exposure is still reasonably likely, each person who is reasonably likely to be exposed to the chemical substance by inhalation in the work area in one or more of the forms listed in paragraph (a)(6) of this section and cited in subpart E of this part for the chemical substance, must be provided with, and is required to wear, a NIOSH- certified respirator from one of the categories listed in paragraph (a)(5) of this section. Refer to 29 CFR 1910.134 and 42 CFR part 84 for requirements on the selection, use, and maintenance of respirators, including establishing respiratory protection program, medical determination, and other administrative and programmatic requirements for respiratory protection.

(5) The following NIOSH-certified respirators meet the requirements for paragraph (a)(4) of this section:

\* \* \*

(xvi) NIOSH-certified N100 (if oil aerosols absent), R100, or P100 filtering facepiece respirator. (APF =10)

(xvii) NIOSH-certified air-purifying half-mask respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters. (APF =10)

(xviii) NIOSH-certified air-purifying half mask respirator equipped with appropriate gas/vapor cartridges. (APF =10)

(xix) NIOSH-certified air-purifying half-mask respirator equipped with appropriate gas/vapor cartridges in combination with N100, R100, or P100 filters or an appropriate canister incorporating N100, R100, or P100 filters. (APF =10)

(xx) NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a half-mask. (APF =10)

(xxi) NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half mask. (APF =10)

(xxii) NIOSH-certified powered air-purifying respirator equipped with a hood or helmet and HEPA filters. (APF =25)

(xxiii) NIOSH-certified powered air-purifying respirator with a hood or helmet equipped with appropriate gas/vapor cartridges. (APF =25)

(xxiv) NIOSH-certified powered air-purifying respirator with a hood or helmet and with appropriate gas/vapor cartridges in combination with HEPA filters. (APF =25)

(xxv) NIOSH-certified powered air-purifying respirator equipped with a loose fitting facepiece and HEPA filters. (APF =25)

(xxvi) NIOSH-certified powered air-purifying respirator equipped with a loose fitting facepiece with appropriate gas/vapor cartridges. (APF =25)

(xxvii) NIOSH-certified powered air-purifying respirator equipped with a loose fitting facepiece with appropriate gas/vapor cartridges in combination with HEPA filters. (APF =25)

(xxviii) NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet. (APF =25)

(xxix) NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece. (APF =25)

(xxx) NIOSH-certified air-purifying full facepiece respirator equipped with N100, R-100, or P-100 filter(s). (APF =50)

(xxxi) NIOSH-certified air-purifying full facepiece respirator equipped with appropriate gas/vapor cartridges or canisters. (APF =50)

(xxxii) NIOSH-certified air-purifying full facepiece respirator equipped with appropriate gas/vapor cartridges in combination with N100, R100, or P100 filters or an appropriate canister incorporating N100, R100, or P100 filters. (APF =50)

(xxxiii) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting half mask and HEPA filters. (APF =50)

(xxxiv) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting half mask and appropriate gas/vapor cartridges or canisters. (APF =50)

(xxxv) NIOSH-certified powered air-purifying respirator with a tight-fitting half mask and appropriate gas/vapor cartridges in combination with HEPA filters. (APF =50)

(xxxvi) NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a half-mask. (APF =50)

(xxxvii) NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece. (APF =50)

(xxxviii) NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting half mask. (APF =50)

(xxxix) NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece. (APF =50)

(xl) NIOSH-certified powered air purifying full facepiece respirator equipped with HEPA filters. (APF=1,000)

(xli) NIOSH-certified powered air purifying full facepiece respirator equipped with appropriate gas/vapor cartridges. (APF=1,000)

(xlii) NIOSH-certified powered air purifying full facepiece respirator equipped with appropriate gas/vapor cartridges in combination with HEPA filters. (APF=1,000)

(xlili) NIOSH-certified powered air-purifying respirator equipped with a hood or helmet and N100, R100, or P100 filters *with evidence demonstrating protection level of 1,000 or greater*. See 40 CFR 721.63(a)(5)(li). (APF=1,000)

(xliv) NIOSH-certified powered air-purifying respirator equipped with a hood or helmet and appropriate gas/vapor cartridges *with evidence demonstrating protection level of 1,000 or greater*. See 40 CFR 721.63(a)(5)(li). (APF=1,000)

(xlv) NIOSH-certified powered air-purifying respirator with a loose-fitting hood or helmet that is equipped with an appropriate gas/vapor cartridge in combination with HEPA filters *with evidence demonstrating protection level of 1,000 or greater*. See 40 CFR 721.63(a)(5)(li). (APF=1,000)

(xlvi) NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece. (APF=1,000)

(xlvii) NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet *with evidence demonstrating protection level of 1,000 or greater*. See 40 CFR 721.63(a)(5)(li). (APF=1,000)

(xlviii) NIOSH-certified pressure-demand supplied-air respirator equipped with a full facepiece. (APF=1,000)

(xlix) NIOSH-certified pressure-demand or other positive-pressure mode (e.g., open/closed circuit) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece. (APF=10,000)

(l) If one of the respirators in paragraph (a)(5)(i) through (a)(5)(xv) is cited for a substance identified in subpart E an employer may substitute a respirator from paragraphs (a)(5)(xvi) through (a)(5)(xlix) as long as its assigned protection factor is equal to or greater than the respirator cited in subpart E for that substance.

(li) Without testing data that demonstrates a level of protection of 1,000 or greater, all air purifying respirators and supplied air respirators with helmets/hoods are to be treated as loose-fitting facepiece respirators with an APF of 25.

(6) When cited in subpart E of this part for a substance, the following airborne form(s) of the substance, in combination or alone, are referenced by paragraphs (a)(1) and (4) of this section:

\* \* \*

(vii) Particulate or aerosol (solids or liquid droplets suspended in a gas; e.g., dust, fume, mist, smoke).

(viii) Gas/vapor.

(ix) Combination particulate and gas/vapor (gas and liquid/solid physical forms are both present, e.g., particulates and acid gases or particulates and organic vapors).

\* \* \*

(c) \* \* \*

(2) If, after receiving a statement of assurance from a recipient under paragraph (c)(1)(ii) of this section, a manufacturer or processor has knowledge that the recipient is engaging in an activity that is not consistent with the implementation of the program specified in paragraph (a) of this section, that person is considered to have knowledge that the person is engaging in a significant new use and is required to follow the procedures in §721.5(d).

\* \* \* \* \*

31. Amend § 721.72 by:

- a. Revising the introductory text paragraph.
- b. Revising paragraph (a) and (1) .
- c. Revising paragraph (b)(5).
- d. Revising paragraph (c)(5), (7) and (9).
- e. Revising paragraph (g)(1) introductory text and paragraphs (g)(1)(i) through (g)(1)(ix).
- f. Adding paragraphs (g)(1)(x) through (g)(1)(xiv).
- g. Revising paragraph (g)(2) introductory text and paragraphs (g)(2)(i) through (g)(2)(v).
- h. Adding paragraphs (g)(2)(vi) through (g)(2)(viii).
- i. Revising paragraphs (g)(3)(i) through (g)(3)(ii).
- j. Adding paragraph (g)(3)(iii).
- k. Revising paragraphs (g)(4)(i) through (g)(4)(iii).
- l. Adding paragraph (g)(4)(iv).
- m. Revising paragraph (h)(1)(ii) introductory text and paragraphs (h)(1)(ii)(A)

through (h)(1)(ii)(I).

n. Adding paragraphs (h)(1)(ii)(J) through (h)(1)(ii)(N).

o. Revising paragraphs (h)(1)(iii)(A) through (h)(1)(iii)(E).

p. Adding paragraphs (h)(1)(iii)(F) through (h)(1)(iii)(H).

q. Revising paragraph (h)(1)(iv) introductory text and paragraphs (h)(1)(iv)(A)

through (h)(1)(iv)(B).

r. Adding paragraph (h)(1)(iv)(C).

s. Revising paragraphs (h)(1)(v)(A) through (h)(1)(v)(C).

t. Adding paragraph (h)(1)(v)(D).

u. Revising paragraph (h)(2)(ii) introductory text and paragraphs (h)(2)(ii)(A) through (h)(2)(ii)(I).

v. Adding paragraphs (h)(2)(ii)(J) through (h)(2)(ii)(N).

w. Revising paragraph (h)(2)(iii) introductory text and paragraphs (h)(2)(iii)(A)

through (h)(2)(iii)(E).

x. Adding paragraphs (h)(2)(iii)(F) through (h)(2)(iii)(H)

y. Revising paragraph (h)(2)(iv) introductory text and paragraphs (h)(2)(iv)(A) and (h)(2)(iv)(B).

z. Adding paragraph (h)(2)(iv)(C).

aa. Revising paragraphs (h)(2)(v)(A) through (h)(2)(v)(C).

bb. Adding paragraph (h)(2)(v)(D).

cc. Adding paragraphs (i) and (j).

The revisions and additions read as follows:



**§ 721.72 Hazard communication program.**

Whenever a substance is identified in subpart E of this part as being subject to this section, a significant new use of that substance is any manner or method of manufacture (including import) or processing associated with any use of that substance without establishing a hazard communication program as described in this section. Paragraphs (a) through (h) apply to SNURs issued before [insert date 60 days after publication in the **Federal Register**]. Paragraphs (i) and (j) apply to SNURs issued on or after [insert date 60 days after publication in the **Federal Register**]. Any person subject to the requirements of paragraphs (a) through (h) have the option of following the requirements of paragraph (i) or using the statements specified in paragraphs (g) or (h).

(a) *Written hazard communication program.* Each employer shall develop and implement a written hazard communication program for the substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, SDSs, and other forms of warning material will be satisfied. The employer must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The employer may rely on an existing hazard communication program, including an existing program established under the Occupational Health and Safety Administration (OSHA) Hazard Communication Standard in 29 CFR 1910.1200 of 2012 to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this paragraph. The written program shall include the following:

(1) A list of each substance identified in subpart E of this part as subject to this section known to be present in the work area. The list must be maintained in the work area

and must use the identity provided on the appropriate SDS for each substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas.

\* \* \*

(b) \* \* \*

(5) If the label or alternative form of warning is to be applied to a mixture containing a substance identified in subpart E of this part as subject to this section in combination with another substance identified in subpart E of this part and/or a substance defined as a “hazardous chemical” under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1910.1200), the employer may prescribe on the label, SDS, or alternative form of warning, the measures to control worker exposure or environmental release which the employer determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under subpart E of this part, the employer must seek a determination of equivalency for such alternative control measures pursuant to § 721.30 before prescribing them under this paragraph (b)(5).

\* \* \*

(c) \* \* \*

(5) If the employer becomes aware of any significant new information regarding the hazards of the substance or ways to protect against the hazards, this new information must be added to the SDS within 3 months from the time the employer becomes aware of the new information. If the substance is not currently being manufactured, processed, or used in the

employer's workplace, the employer must add the new information to the SDS before the substance is reintroduced into the workplace.

\* \* \*

(7) The employer must maintain a copy of the SDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas. (Easy and immediate electronic access and other alternatives to maintaining paper copies of the safety data sheets are permitted as long as complete and accurate versions of the SDS are available immediately to employees in each workplace by such options.)

\* \* \*

(9) The SDS must be in English; however, the information may be repeated in other languages.

\* \* \*

(g) \* \* \*

(1) Human health hazard statements:

(i) Causes skin irritation.

(ii) Respiratory complications. (You may also use paragraph (g)(1)(x) of this section for this designation.).

(iii) Central nervous system effects. (You may also use paragraph (g)(1)(xi) of this section for this designation but you must include this specific effect.)

(iv) Internal organ effects. (You may also use paragraph (g)(1)(xi) of this section for this designation.)

(v) Birth defects. (You may also use paragraph (g)(1)(xii) of this section for this designation but you must include this specific effect.)

(vi) Reproductive effects. (You may also use paragraph (g)(1)(xii) of this section for this designation but you must include this specific effect.)

(vii) May cause cancer.

(viii) Immune system effects. (You may also use paragraph (g)(1)(xi) of this section for this designation but you must include this specific effect.)

(ix) Developmental effects. (You may also use paragraph (g)(1)(xii) of this section for this designation but you must include this specific effect.)

(x) May cause allergy or asthma symptoms or breathing difficulties if inhaled.

(xi) May cause damage to organs <...> through prolonged or repeated exposure.  
<...> (State all organs identified in subpart E of this part for this substance.).

(xii) May damage fertility or the unborn child <...>.  
<...> (State specific effect identified in subpart E of this part for this substance.)

(xiii) May cause an allergic skin reaction.

(xiv) Causes eye irritation.

(2) Human health hazard precautionary statements:

(i) Avoid skin contact. (You may also use paragraph (g)(2)(vi) of this section for this designation.)

(ii) Avoid breathing substance. (You may also use paragraph (g)(2)(viii) of this section for this designation.)

(iii) Avoid ingestion.

(iv) Use respiratory protection. (You may also use paragraph (g)(2)(vii) of this section for this designation.)

(v) Use skin protection. (You may also use paragraph (g)(2)(vi) of this section for this designation.)

(vi) Wear protective gloves/protective clothing/eye protection/face protection.  
(Chemical manufacturer or distributor to specify type of equipment, as required.)

(vii) Wear respiratory protection. (Chemical manufacturer or distributor to specify equipment as required.)

(viii) Avoid breathing dust/fume/gas/mist/vapors/spray. (Chemical manufacturer or distributor to specify applicable conditions.)

(3) \* \* \*

(i) Toxic to fish. (You may also use paragraph (g)(3)(iii) of this section for this designation.)

(ii) Toxic to aquatic organisms. (You may also use paragraph (g)(3)(iii) of this section for this designation.)

(iii) Toxic to aquatic life.

(4) \* \* \*

(i) Disposal restrictions apply. (You may also use paragraph (g)(4)(iv) of this section for this designation.)

(ii) Spill clean-up restrictions apply. (You may also use paragraph (g)(4)(iv) of this section for this designation.)

(iii) Do not release to water. (You may also use paragraph (g)(4)(iv) of this section for this designation.)

(iv) Dispose of contents/container to ... (Specify disposal requirements in subpart E of this part and whether they apply to contents, container or both.)

\* \* \*

(h) (1) \* \* \*

(ii) *Human health hazard statements.*

(A) Causes skin irritation.

(B) Respiratory complications. (You may also use paragraph (h)(1)(ii)(J) of this section for this designation.)

(C) Central nervous system effects. (You may also use paragraph (h)(1)(ii)(K) of this section for this designation but you must include this specific effect.)

(D) Internal organ effects. (You may also use paragraph (h)(1)(ii)(K) of this section for this designation.)

(E) Birth defects. (You may also use paragraph (h)(1)(ii)(L) of this section for this designation but you must include this specific effect.)

(F) Reproductive effects. (You may also use paragraph (h)(1)(ii)(L) of this section for this designation but you must include this specific effect.)

(G) Cancer.

(H) Immune system effects. (You may also use paragraph (h)(1)(ii)(K) of this section for this designation but you must include this specific effect.)

(I) Developmental effects. (You may also use paragraph (h)(1)(ii)(L) of this section for this designation but you must include this specific effect.)

(J) May cause allergy or asthma symptoms or breathing difficulties if inhaled.

(K) May cause damage to organs <...> through prolonged or repeated exposure.

<...> (state all organs identified in subpart E of this part for this substance.)

(L) May damage fertility or the unborn child <...> .

<...> (state specific effect identified in subpart E of this part for this substance.)

(M) May cause an allergic skin reaction.

(N) Causes eye irritation.

(iii) *Human health hazard precautionary statements.*

(A) Avoid skin contact. (You may also use paragraph (h)(1)(iii)(F) of this section for this designation.)

(B) Avoid breathing substance. (You may also use paragraph (h)(1)(iii)(H) of this section for this designation.)

(C) Avoid ingestion.

(D) Use respiratory protection. (You may also use paragraph (h)(1)(iii)(G) of this section for this designation.)

(E) Use skin protection. (You may also use paragraph (h)(1)(iii)(F) of this section for this designation.)

(F) Wear protective gloves/protective clothing/eye protection/face protection.  
(Chemical manufacturer or distributor to specify type of equipment, as required.)

(G) Wear respiratory protection. (Chemical manufacturer or distributor to specify equipment as required.)

(H) Avoid breathing dust/fume/gas/mist/vapors/spray. (Chemical manufacturer or distributor to specify applicable conditions.)

(iv) *Environmental hazard statements.*

(A) Toxic to fish. (You may also use paragraph (h)(1)(iv)(C) of this section for this designation.)

(B) Toxic to aquatic organisms. (You may also use paragraph (h)(1)(iv)(C) of this section for this designation.)

(C) Toxic to aquatic life.

(v) *Environmental hazard precautionary statements*. Notice to Users:

(A) Disposal restrictions apply. (You may also use paragraph (h)(1)(v)(D) of this section for this designation)

(B) Spill clean-up restrictions apply. (You may also use paragraph (h)(1)(v)(D) of this section for this designation)

(C) Do not release to water. (You may also use paragraph (h)(1)(v)(D) of this section for this designation.)

(D) Dispose of contents/container to ... (Specify disposal requirements in subpart E of this part and whether they apply to contents, container or both.)

\* \* \*

(2) \* \* \*

(ii) *Human health hazard statements*.

(A) Causes skin irritation.

(B) Respiratory complications. (You may also use paragraph (h)(2)(ii)(J) of this section for this designation.)

(C) Central nervous system effects. (You may also use paragraph (h)(2)(ii)(K) of this section for this designation but you must include this specific effect.)

(D) Internal organ effects. (You may also use paragraph (h)(2)(ii)(K) of this section for this designation.)



(E) Birth defects. (You may also use paragraph (h)(2)(ii)(L) of this section for this designation but you must include this specific effect.)

(F) Reproductive effects. (You may also use paragraph (h)(2)(ii)(L) of this section for this designation but you must include this specific effect.)

(G) May cause cancer.

(H) Immune system effects. (You may also use paragraph (h)(2)(ii)(K) of this section for this designation but you must include this specific effect.)

(I) Developmental effects. (You may also use paragraph (h)(2)(ii)(L) of this section for this designation but you must include this specific effect.)

(J) May cause allergy or asthma symptoms or breathing difficulties if inhaled.

(K) May cause damage to organs <...> through prolonged or repeated exposure.

<...> (state all organs identified in subpart E for this substance.)

(L) May damage fertility or the unborn child <...>.

<...> (state specific effect identified in subpart E for this substance.)

(M) May cause an allergic skin reaction.

(N) Causes eye irritation.

(iii) *Human health hazard precautionary statements.*

(A) Avoid skin contact. (You may also use paragraph (h)(2)(iii)(F) of this section for this designation.)

(B) Avoid breathing substance. (You may also use paragraph (h)(2)(iii)(H) of this section for this designation.)

(C) Avoid ingestion.

(D) Use respiratory protection. (You may also use paragraph (h)(2)(iii)(G) of this section for this designation.)

(E) Use skin protection. (You may also use paragraph (h)(2)(iii)(F) of this section for this designation.)

(F) Wear protective gloves/protective clothing/eye protection/face protection.  
(Chemical manufacturer or distributor to specify type of equipment, as required.)

(G) Wear respiratory protection. (Chemical manufacturer or distributor to specify equipment as required.)

(H) Avoid breathing dust/fume/gas/mist/vapors/spray. (Chemical manufacturer or distributor to specify applicable conditions.)

(iv) *Environmental hazard statements.*

(A) Toxic to fish. (You may also use paragraph (h)(2)(iv)(C) of this section for this designation.)

(B) Toxic to aquatic organisms. (You may also use paragraph (h)(2)(iv)(C) of this section for this designation.)

(C) Toxic to aquatic life.

(v) *Environmental hazard precautionary statements.* Notice to Users:

(A) Disposal restrictions apply. (You may also use paragraph (h)(2)(v)(D) of this section for this designation.)

(B) Spill clean-up restrictions apply. (You may also use paragraph (h)(2)(v)(D) of this section for this designation.)

(C) Do not release to water. (You may also use paragraph (h)(2)(v)(D) of this section for this designation.)

(D) Dispose of contents/container to ... (Specify disposal requirements in subpart E of this part and whether they apply to contents, container or both.)

(i) *Written hazard communication program.* Each employer shall develop and implement a written hazard communication program for the substance in each workplace in accordance with 29 CFR 1910.1200.

(j) *Human health, environmental hazard, exposure, and precautionary statements.* In addition to the requirements for the hazard communication program specified in paragraph (i), whenever referenced in subpart E of this part for a substance, the following human health and environmental hazard, exposure, and precautionary statements shall appear as specified in paragraph (i) of this section.

(1) Human health hazard statements:

(i) Causes skin irritation.

(ii) May cause cancer.

(iii) Immune system effects.

(iv) Developmental effects.

(v) May cause allergy or asthma symptoms or breathing difficulties if inhaled.

(vi) May cause damage to organs <...> through prolonged or repeated exposure.

<...> (state all organs identified in subpart E for this substance.)

(vii) May damage fertility or the unborn child <...> .

<...> (state specific effect identified in subpart E for this substance.)

(viii) May cause an allergic skin reaction.

(ix) Causes eye irritation.

(2) Human health hazard precautionary statements:

(i) Avoid ingestion.

(ii) Wear protective gloves/protective clothing/eye protection/face protection.

(Chemical manufacturer or distributor to specify type of equipment, as required.)

(iii) Wear respiratory protection.

(Chemical manufacturer or distributor to specify equipment as required.)

(iv) Avoid breathing dust/fume/gas/mist/vapors/spray.

(Chemical manufacturer or distributor to specify applicable conditions.)

(3) Environmental hazard statements: This substance may be:

(i) Toxic to aquatic life.

(ii) Very toxic to aquatic life.

(iii) Harmful to aquatic life.

(iv) Very toxic to aquatic life with long term effects.

(v) Toxic to aquatic life with long lasting effects.

(vi) Harmful to aquatic life with long lasting effects.

(vii) May cause long lasting harmful effects to aquatic life.

(4) Environmental hazard precautionary statements: Notice to users:

(i) Avoid release to the environment (if this is not the intended use.)

(ii) Collect spillage.

(iii) Dispose of contents/container to ... (Specify disposal requirements in subpart E of this part and whether they apply to contents, container or both.)

32. Amend § 721.80 by:

a. Removing the phrase “or import” wherever it appears in the section.

b. Removing the phrase “and importation” wherever it appears in the section.

- c. Removing the phrase “or importer” wherever it appears in the section.
- d. Removing the word “manufacture” wherever it appears and add in its place the word “manufacturing”.

33. In § 721.85, remove the word “supercede” wherever it appears and add in its place the word “supersede”.

34. Amend § 721.91 by:

- a. Revising the introductory paragraph, and
- b. Adding paragraph (a)(7).

The revision reads as follows:

**§ 721.91 Computation of estimated surface water concentrations: Instructions.**

These instructions describe the use of the equation specified in § 721.90(a)(4), (b)(4), and (c)(4) to compute estimated surface water concentrations which will result from release of a substance identified in subpart E of this part. The equation shall be computed for each site using the stream flow rate appropriate for the site according to paragraph (b) of this section, and the highest number of kilograms calculated to be released for that site on a given day according to paragraph (a) of this section. Two variables shall be considered in computing the equation, the number of kilograms released, and receiving stream flow.

(a) \* \* \*

(7) When a substance is designated in subpart E of this part with a specific control technology and a percentage removal of the substance from wastewater resulting from use of the specified control technology, you may subtract that percentage from the highest expected daily release if that control technology is applied.

\* \* \* \* \*

5. In § 721.100, remove the phrase “manufacturers, importers, and processors” and add in its place “manufacturers and processors”.

36. Amend § 721.125 by revising the introductory paragraph, paragraph (a), (c), and (j) to read as follows:

**§ 721.125 Recordkeeping requirements.**

At the time EPA adds a substance to subpart E of this part, EPA will specify appropriate recordkeeping requirements which correspond to the significant new use designations for the substance selected from subpart B of this part. Each manufacturer and processor of the substance shall maintain the records for 5 years from the date of their creation. In addition to the records specified in §721.40, the records whose maintenance this section requires may include the following:

(a) Records documenting the manufacturing volume of the substance and the corresponding dates of manufacture.

\* \* \*

(c) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or processing to whom the manufacturer or processor directly sells or transfers the substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date.

\* \* \*

(j) Records documenting compliance with any applicable disposal requirements under §721.85, including the method of disposal, location of disposal sites, dates of disposal, and volume of the substance disposed. Where the estimated disposal volume is not known to or reasonably ascertainable by the manufacturer or processor, that person must maintain other

records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements.

\* \* \* \*

37. Amend § 721.160 by:

- a. Removing in paragraph (a)(1) the phrase “and import”.
- b. Removing in paragraph (a)(2) the phrase “or import”.

**PART 723--[AMENDED]**

38. The authority citation for part 723 continues to read as follows:

**Authority:** 15 U.S.C. 2604.

39. Amend § 723.50 by:

- a. Revising paragraph (a)(1) introductory text.
- b. Revising paragraph (e)(2)(xi)(A).
- c. Adding paragraph (e)(2)(xiii).

The revisions read as follows:

**§ 723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures**

(a)\* \* \*

(1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of:

\* \* \*

(e) \* \* \*

(2) \* \* \*

(xi)\* \* \*

(A) The manufacturer intends to manufacture the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of this section.

\* \* \*

(xiii) Safety Data Sheet (§ 720.45(i)).

\* \* \* \* \*

40. Amend § 723.175 by:

- a. Removing in paragraph (f)(2)(iii), the word “imprevious” and add in its place “impervious”.
- b. Removing in paragraph (g), the word “chemcial” and add in its place “chemical”.
- c. Removing in paragraph (h)(2), the phrase “chemcial substance” and add in its place “chemical substance”.
- d. Removing in paragraph (i)(1)(ii)(A), the word “disagram” and add in its place “diagram”.
- e. Removing in paragraph (i)(1)(ii)(C), the word “indentify” and add in its place “identify”.
- f. Removing in paragraph (i)(1)(iii), the word “chemcial” and add in its place “chemical”.

41. Amend § 723.250 by:

- a. Removing in paragraph (e)(3) the phrase “composition, complex” and add in its place “composition, complex”.



b. Removing in paragraph (j)(1), the phrase “or import”.

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